

SUPPLEMENTAL
Notice of Allowability

Application No.

10/629,321

Examiner

D. L. Jones

Applicant(s)

DELANEY ET AL.

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/24/07.
2. ☒ The allowed claim(s) is/are 1-3,6-23 and 25-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>9/24/07</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Bret Field on September 24, 2007.

The application has been amended as follows.

Please replace claim 1 with the following.

1. (Currently Amended) A method of producing a flowable composition that sets into a calcium phosphate mineral product, said method comprising:

- (a) a setting fluid;
- (b) dry reactants comprising a calcium source and a phosphate source; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate product wherein said water-soluble contrast agent comprises a salt of a radio-opaque element;

to produce said flowable material that sets into a calcium phosphate mineral product that includes atoms of said radio-opaque element incorporated into said mineral product.

Please cancel claim 4.

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Please replace claim 6 with the following.

6. (Currently Amended) The method according to claim 1 wherein said radio-opaque element is one that is incorporated into a calcium phosphate apatite structure of said calcium phosphate containing product.

Please replace claim 7 with the following.

7. (Currently Amended) The method according to claim 1 wherein said radio-opaque element is chosen from barium, oxalate, zirconium, tantalum, and tungsten.

Please replace claim 25 with the following.

25. (Currently Amended) A kit for use in preparing a flowable composition that sets in an in vivo fluid environment into a calcium phosphate mineral product comprising calcium phosphate molecules, said kit comprising:

- (a) dry reactants comprising a calcium source and a phosphate source;
- (b) a setting fluid or components for producing the same; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate mineral product wherein said water-soluble contrast agent comprises a salt of a radio-opaque element; and wherein said calcium phosphate mineral product includes atoms of said radio-opaque element incorporated into said mineral product.

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Please replace claim 26 with the following.

26. (Currently Amended) A packaged calcium phosphate cement, said packaged cement comprising:

a tubular element separated into a first compartment and at least one additional compartment by a removable barrier;

(i) dry reactants comprising a source of calcium and phosphate present in said first compartment;

(ii) a setting fluid or components thereof present in said at least one additional compartment; and

(iii) a water-soluble contrast comprising a radio-opaque element other than calcium that is incorporated into a calcium phosphate mineral product wherein said water-soluble contrast agent comprises a salt of a radio-opaque element, wherein said calcium phosphate mineral product includes atoms of said radio-opaque element incorporated into said mineral product, wherein said calcium phosphate mineral product is produced upon combination of said dry reactants and setting fluid, wherein said water-soluble contrast agent is present in either said first compartment, said at least one additional compartment or in a second additional compartment.

COMMENTS/NOTES

The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a product or method of producing the composition as set forth in independent claims 1, 15, 25, and 26 wherein the water soluble contrast

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agent comprises a radio-opaque other than calcium and wherein the said water soluble contrast agent comprises a salt of a radio-opaque element.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
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September 24, 2007